

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Offic**

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APPLICATION NO.	FILED DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/932,227 09/17/97 FOSSEL

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IM62/1104

EXAMINER

MULLIS, J

ART UNIT

PAPER NUMBER

1711

II

DATE MAILED: 11/04/99

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

**Office Action Summary**

Application No. <b>08/932,227</b>	Applicant(s) <b>Fossil</b>
Examiner <b>Jeffrey Mullis</b>	Group Art Unit <b>1711</b>

 Responsive to communication(s) filed on Aug 10, 1999 This action is **FINAL**. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims** Claim(s) 33-60 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

 Claim(s) \_\_\_\_\_ is/are allowed. Claim(s) 33-60 is/are rejected. Claim(s) \_\_\_\_\_ is/are objected to. Claims \_\_\_\_\_ are subject to restriction or election requirement.**Application Papers** See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner. The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved. The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119** Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

 Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)** Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). 10 Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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All remaining rejections and/or objections follow.

Claims 39-41, 47-50 and 56-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear whether or not the materials in claims 39 and 47, etc. are meant to be used as alternatives or in combination since this is not stated in the claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

*d 39-41, 47-50, 56, 59, 60*  
Claims 33-34, 38, 39, 51-54, 56, 59 and 60 are rejected

*57, 58,*  
under 35 U.S.C. 102(a) as anticipated by or, in the alternative,

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under 35 U.S.C. 103(a) as obvious over Weuffen et al. (USP 5,629,002).

See the Office action of Paper No. 6 page 4 lines 5 et seq.

Claims 33-34 and 39 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hechtman (USP 5,595,753).

See the Office action of Paper No. 6 at the paragraph bridging pages 4 and 5 et seq.

Claims 33-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garfield et al. in view of Hechtman (USP 5,595,753), Altadonna (USP 5,853,768), Cooke et al. (USP 5,428,070), Saavedra et al. (USP 5,632,981) and Cooper et al. (USP 5,581,581).

See the previous Office action at the paragraph bridging pages 3 and 4 et seq.

Cooper et al. discloses that ionic surfactants such as sodium oleate function to increase penetration of polar materials. Note the last two complete paragraphs on page 59 and reference 11 on page 61.

It would have been obvious to a practitioner having ordinary skill in the art at the time of the invention to add ionic surfactants (i.e. salts) such as sodium oleate to the composition of the primary reference motivated to enhance penetration as taught by the secondary reference Cooper absent any showing of surprising or unexpected results.

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Applicant's arguments filed 8-10-99 have been fully considered but they are not persuasive.

In the rejection under 35 U.S.C. § 112, second paragraph applicant argues that "This claim is neither in the alternative, nor is it in combination". However it appears to the Examiner that there are only two possibilities, namely that the materials recited in these claims are to be used together or are to be used separately. Therefore it is not clear how the claim can be said to be neither in the alternative, nor in combination.

Applicant's remaining remarks regarding the rejections under 35 U.S.C. § 112 are moot since all other rejections under 35 U.S.C. § 112 have been withdrawn.

With regard to the rejection under 35 U.S.C. § 102 relying upon Weuffen et al., applicant argues that this reference discloses the use of thiocyanates as the active ingredient. However the fact that the reference does not explicitly disclose that arginine is the active ingredient is immaterial. All that is required is that such would be inherent. Applicant's specification discloses that L-arginine in combination with salts when applied to the skin causes L-arginine to migrate to the skin and that the L-arginine inherently causes an increase in nitric oxide production. In any case it is not clear what the L-arginine is doing in Weuffen's composition if it does not penetrate the skin. It does not appear to the Examiner that it

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would be reasonable that a medicament which did not penetrate the skin at all would be very effective. To be sure Weuffen does not disclose explicitly that the nitric oxide is the medicament responsible for hair growth but in any case, the arginine is a component of the composition and whatever its effect is intended to be, it does not appear reasonable that such an effect could be achieved without any penetration of the skin. Each and every element of applicant's claims is therefore present although not necessarily explicitly disclosed.

With regard to Hechtman, the Examiner acknowledges that applicant's invention is a method for delivering L-arginine. Applicant argues that the electrolyte in Hechtman is not limited to an ionic strength which is high enough to create an hostile biophysical environment. However the term "hostile biophysical environment" does not appear in the claims. Rather, the claims merely recite a concentration of ionic salt sufficient to create an ionic environment which causes a substance to migrate from the vehicle to the skin where the substance is absorbed. However as with Weuffen et al. above, it does not appear reasonable that the arginine of patentees is not absorbed. In any case it is applicant's burden to show that applicant's property or function is not present in the reference as set out above and in In re Fitzgerald et al.

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With regard to Garfield, applicant argue that there is no mention of an hostile biophysical environment used in combination with a nitric oxide precursor such as L-arginine. However one cannot attack a reference individually where a rejection is based on a combination of references. Applicant's statement that "Therefore this reference alone or in combination with the other cited art does not render the instant invention obvious" is not understood in that applicant's arguments up to this point only discuss Garfield, not the other references.

With regard to Saavedra, this reference has not been relied upon for any disclosure of creation of an hostile biophysical environment.

With regard to Cooke et al., this reference has been relied upon solely for the teaching of the use of arginine glutamate.

With regard to Altadonna, this reference specifically discloses that "iodide salts enhance penetration of the pain relief components of the composition". Note the Abstract in this regard. Hence it is clear that the iodide in Altadonna enhances penetration of the skin whatever other function the iodide may serve. Applicant argues that Altadonna uses material such as menthol and camphor, etc. However it is not the position of the Examiner that Altadonna discloses all features of applicant's claims. Nor is it clear how it can be said that this reference teaches away from applicant's invention merely because some

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features of the reference are different from those of applicant's claims.

Applicant argues that the Examiner has failed to support the statements on page 20 of applicant's remarks. However all the statements therein are present in the references. Thus Cooke et al. explicitly discloses that arginine glutamate functions to release nitric oxide in tissue; Altadonna explicitly discloses that iodide increases skin penetration; Saavedra et al. explicitly discloses application to the skin by topical application. Applicant argues that "To the contrary neither Garfield, Saavedra, Altadonna nor any of the other cited documents suggest providing an hostile biophysical environment to facilitate the migration of L-arginine from a delivery vehicle to the target tissue. However this is piecemeal analysis of the above rejection. Note In re Keller, 208 USPQ 871 (CCPA 1981) where it was held that "as characterized by appellant, the Cywinski affidavit offered as objective evidence of non-obviousness "concerns itself mainly with the question of whether the Walsh et al. article suggests the use of digital timing in a cardiac pacer" but one cannot show non-obviousness by attacking references individually where, as here the rejections are based on combinations of references. The only reference relied upon for enhancement of skin penetration is Saavedra. It is immaterial to patentability that Altadona does not explicitly

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disclose that potassium iodide can be used with L-arginine to enhance the penetration of the L-arginine. It is unnecessary that such an explicit disclosure be present. Note In re Scheckler, 168 USPQ 716 (CCPA 1971) where it was held that "It is, of course, not necessary that either Barnes or Dryden actually suggest, expressly or in some many words, the changes or possible improvements appellant has made." Applicants argue that "As has been stated previously, none of these documents are based on the discovery that including a carrier with excess salt induces L-arginine to preferentially migrate from the delivery vehicle to produce the beneficial effects attributed to nitric oxide". However it is not the position of the Examiner that any reference explicitly discloses all elements of applicant's claims, nor is a reference relied upon under 35 U.S.C. § 103 in which the reference explicitly discloses all elements of a claim. Rather such a reference would be used to reject applicant's claims under 35 U.S.C. § 102. Applicant argues that the references teach away from the combination. However applicant has not been clear how the references teach away from the combination as relied upon by the Examiner. Applicant argues that there must be some suggestion of desirability in the combination. However as set out in the above rejections, the references do suggest the desirability of the proposed modifications. Thus Altadonna suggests that increased penetration may be achieved by use of

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potassium iodide; Saavedra also discloses a method of achieving the goals of Garfield, namely that of treating impotence. None of the suggestions are present anywhere except in the references. Applicant's disclosure has not been relied upon. The factual basis for the Examiner's rejection and the reasons for obviousness are clearly set out in the rejection and are based upon the benefits disclosed by the references.

Applicant argues that "The fact that those skilled in the art have not implemented the use of an hostile biophysical environment to derive L-arginine in a tissue, indicates the present invention is not obvious". However this is a generic argument for patentability wherever the prior art does not disclose (i.e. anticipate) all limitations of a claim.

Applicant argues that the mere fact that Hechtman and Weuffen disclose arginine and salt in no way implies that an hostile biophysical environment is inherently present. Firstly, the phrase "hostile biophysical environment" is not present in the claims. Applicant's own specification however discloses a combination of salts and arginine function in applicant's invention. Applicant argues of course that the concentration of salt must be high enough to create an hostile biophysical environment. However again there is nothing in the claims about an hostile biophysical environment. Rather the claims merely recite that the concentration of salt must be sufficient to

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create an ionic environment which causes a substance to migrate from the vehicle to the skin while the substance is absorbed. It reasonably appears that absorption of the arginine of the references relied upon for anticipation inherently takes place given that a medicament is likely to have little effect without absorption. In any case it is applicant's burden to prove that the concentration of salts in the reference is not high enough to cause absorption. Applicant argues that the use of an ionic solution of sufficient concentration is analogous to the term "hostile biophysical environment". Assuming this is so, it is not clear that such a function is not inherent in the references. It is not clear what the differences between Hechtman and the claims are, if any and therefore it is not clear that such differences are not obvious. The same can be said for Weuffen et al.

Applicant alleges that a number of rejections in the first Office action are repeated in the present Office action as set out on page 26 of applicant's remarks. In fact page 26 of applicant's remarks does not contain a number of rejections as alleged or even a single rejection. Only a portion of a rejection appears on page 26 of applicant's remarks. The rejection under 35 U.S.C. § 103 relying upon Garfield as a primary reference in Paper No. 8 of 5-10-99 was not made earlier nor could it have been made earlier since this rejection relies

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upon Altadonna which did not issue prior to the Office action of Paper No. 6 and therefore could not have possibly been made prior to Paper No. 8. With regard to Cooper et al., newly cited, this reference came to the Examiner's attention by review of U.S. Patent 5,925,372 which cited this reference in its specification. This patent was not previously available since it had not issued prior to the present Office action.

It is not the position of the Examiner that Garfield et al., Hechtman and Cooke et al. by themselves render the claims obvious.

This Office action is not being made FINAL.

Any inquiry concerning this communication should be directed to Jeffrey Mullis at telephone number (703) 308-2820.

J. Mullis:cdc

November 3, 1999

JEFFREY C. MULLIS  
PRIMARY EXAMINER  
GROUP 1200/74

